

STATUS OF CLAIMS

Claims 1-21 are presently pending in the application. Support for the amendment of claims 1, 2, 5 and 11 can be found in paragraph [0032] of the specification. No new matter is added.

REMARKS

Objection to Drawings

In the Office Action, the Examiner objects to FIGS 18A-18C for various reasons. The objections are believed to be moot in view of the amendments made herein to the drawings.

The Examiner also objects to the drawings as failing to show every feature of the invention specified in the claims. Specifically, the Examiner requests Applicant to show the valve seats, diaphragms and other internal parts of the valve *configured in the first position, second position, and default neutral position* of the valve in the drawings or to cancel the features from the claims.

According to the Office Action, the Examiner is objecting to the drawings under rule 37 CFR 1.83(a), which clearly states that every feature of the invention specified in the claims must be shown in the drawings.

It is further noted from 37 CFR 1.81(a), however, that the applicant is required to furnish a drawing of his or her invention only “where necessary for the understanding of the subject matter sought to be patented”. In this regard, it is noted that a great number of patents issue from the USPTO on a weekly basis that contain no drawings whatsoever.

The present application clearly meets the requirements of 35 USC 113 and 37 CFR 1.81 *et seq.* In this regard, it is respectfully submitted that one of ordinary skill in the art would readily understand the three possible positions of the valve that is described and claimed herein, for example, by following the instructions in the specification regarding the construction of such a valve. The valve according to one embodiment, is exemplified, for example, in Fig. 9, and the valve in the first position, second position, and default position are illustrated, for example, in FIGS. 17A, 17B, and 17C, respectively, in the form of a labeled representation in accordance with 37 C.F.R. 1.83(a). Details including the valve seats, diaphragms and other internal parts of the valve are shown in Figs. 11 and 18, according to an embodiment of the invention.

One of skill in the art would readily understand that the valve 1) can be pneumatically operated to open the first valve seat while closing the second valve seat, 2) can be pneumatically operated to close the first valve seat while opening the second valve seat, or 3) can occupy a central position where the first and second valve seats are open (the default neutral position) when supply pressure operating the valve is removed.

As explained previously, in the DETAILED DESCRIPTION of the specification, Applicant provides not only the structure of the new three-way valve of the present invention (see Figs. 9, 11 and 18), but also provides details regarding a simple method of manufacture of such a device, based on an existing three-way valve and provides illustrative drawings of both the prior art and the improved valve of the present invention. *See* paragraphs [0032] to [0033] and [0040] to [0043].

Based on the description, one of ordinary skill in the art would understand how the valve returns to its neutral state without the use of a spring return mechanism. Specifically, Applicant has drawn the Examiner's attention to the default structure of Applicant's device in contrast to prior art three-way valves. In the prior art Takasago three-way valve of Figures 2-8, due to the presence of the spring return in the valve (see Figure 5), there is ***always an actuating force on the valve, even when the supply pressure operating the valve is removed, e.g., when the valve is not in use*** (see paragraph [0002] of the Background and see also the October 10, 2006 Amendment and Response in which Applicant describes in great detail the mechanics of the Takasago valve with a spring return).

The prior art Takasago three-way valve, as can be seen from FIG 5 (prior art), provided below with annotations, is a pneumatically activated valve (via pneumatically activated plunger 63) with a spring return 61.

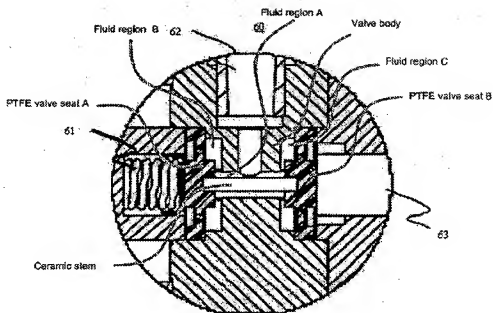


Fig. 5

The valve contains an assembly that includes two PTFE valve diaphragm seals mechanically interlocked with a small ceramic stem (“the Takasago assembly”). As can be seen from FIG 5, the PTFE valve diaphragm seals are *fixed* such that they cannot move horizontally without deformation. Moreover, the PTFE diaphragm seals are elastic and in the absence of any horizontal force (i.e., pneumatic force or spring force), would be centered with respect to the valve body (which is shown in right-hand downward cross-hatching) such that a gap is created between the valve diaphragm seals and the valve seats such that both valve seats are *open*. However, when the plunger 63 of FIG 5 is pneumatically activated, it drives the assembly to the left. This overcomes the force being exerted by the spring return 61 and allows the PTFE valve seat A to pull away from the valve body, resulting in fluid communication between fluid region A (which is connected to a first common port) and fluid region B (which is connected to a second port). This also pushes the PTFE valve diaphragm seal B against the valve seat of the valve body, precluding fluid communication between fluid region A and fluid region C (which is connected to a third port). On the other hand, when the pneumatic pressure is *removed*, the assembly is driven to the *right* by the spring return 61, forcing the PTFE valve diaphragm seal A against the valve seat of the valve body, and preventing fluid communication between fluid region A and fluid region B. The PTFE valve diaphragm seal B, on the other hand, is pulled

away from the valve body, allowing fluid communication between fluid region A and fluid region C. Thus, due to the presence of the spring return in the valve of FIG 5, there is ***always an actuating force***, even when the supply pressure operating the valve is removed (e.g., when the valve is not in use). Consequently, there is never a situation in which the assembly is not being urged to left or right, and thus the assembly is never allowed to become centered with respect to the valve body (due to the elastic rebound of the PTFE material). As such, there is never a situation where both valve diaphragm seals are open causing a gap opening between the seals and the valve seats (i.e., at its “equilibrium” position). Moreover, when the supply pressure operating the valve is removed from the valve of FIG 5, the PTFE valve A is forced against the valve body by the spring return, and many times results in the valve becoming glued shut in this position.

All of the above is in contrast to the present invention which is mechanically configured such that “all valve seats of the medical device [are] ***open*** when the unit is not in use.” (paragraph [0005]) (emphasis added). Referring to Figs. 9, 11 and 18, which shows an embodiment of the present invention, the three-way valve of the present invention has two ends, which remain open when the unit is not in use, i.e., unit is in a default neutral state. Both valve seats are pneumatically driven and there is no spring return. Thus, when the pneumatic force is removed from the valve (e.g., when the valve is not in use), the assembly is neither forced to the left nor to the right, allowing the assembly to return to its centered “equilibrium” position when both valve seats are open. This completely opens the valve (i.e., establishing fluid communication between fluid region A and fluid region B at the same time as establishing fluid communication between fluid region A and fluid region C). More importantly, when the spray coat machine of the present invention is not in use, ***neither valve seat is held closed, which eliminates the possibility of the valve becoming glued shut.*** See paragraph [0033].

As described in the specification with respect to Figure 9, “[F]our millimeter tubing 71 connects to ***one end*** of the three-way valve, which is coupled to a nitrogen source for controlling the valve. Six millimeter tubing 74 connects to the ***other end*** of the three-way valve, which is also coupled to a nitrogen source for controlling the valve. According to one aspect of the present invention, when the nitrogen pressure is removed, a ***default neutral state*** is achieved in which ***both valve seats of the three-way valve are open***, thereby preventing solids buildup or gluing of the valve seats closed by drying agents. Three valve ports are available 73, 75 and 76

for use to couple to a reservoir, a spray nozzle and syringe, or other applications requiring three valves.” (emphasis added) (paragraph [0025]).

The prior art spring return mechanism is not necessary in the valve of the invention because Applicant’s device contains a second pneumatic return. As shown in Figure 11, Applicant’s device is mechanically structured so as “to make the valve 70 operate with a second pneumatic return rather than a spring return mechanism.” Thus, where a spring return mechanism would normally be located, Applicant’s device provides a second pneumatic return. Instead of the spring return mechanism, the device provides other structural elements that allow the device to still function without such spring return mechanism. This is achieved in Applicant’s invention, for example, by adding the elements shown outside the “box” illustrated in Figure 11: “a plunger 77 is added along with an air pressure diaphragm 78, a modified valve bracket 30, and a 6-millimeter tubing interconnection 74.” (paragraph [0032]). Because the valve is fully pneumatically driven, when the pneumatic force is removed from the valve (e.g., when the valve is not in use), the assembly of valve diaphragm seals and valve seats interlocked with a small ceramic stem is neither forced to the right nor to the left, allowing the assembly to return to its centered “equilibrium” position wherein no pressure/energy is exerted. A great advantage of having a device where the valve seats of the three-way valve are open in a default neutral state is that it prevents the possibility of the valve becoming glued shut by drying agents, which has been a problem in prior art valves wherein the valve seat is closed in its neutral state (paragraph [0025]).

An overview of the types of changes that would be need to be made from a prior art Takasago three-way valve to result in Applicant’s invention is provided in paragraph [0010], which states that it entails “disassembling a first symmetric three-way valve and reassembling the first valve backwards, and replacing a spring return of a second identical valve with the backwards-assembled first valve. In addition, the method includes attaching the backwards-assembled first valve to a valve body of the second valve using a bracket from the second valve, as well as drilling out and counter boring two tapped holes in a valve bracket and using the valve bracket to attaching the pneumatic plunger portion from the first valve to a valve body of the second valve.”

In this regard, it is noted that the description alone without any drawings is sufficient to provide one of ordinary skill in the art with an understanding of the subject matter sought to be

patented. The fact that Applicant has provided drawings, however, leaves no doubt that the statutory requirements have been met.

Objection to the Specification

The amendment filed 7/21/2009 is objected to under 35 U.S.C. 132(a) because it allegedly introduces new matter into the disclosure. This objection is moot in view of the above amendment to the specification.

Rejection Under 35 U.S.C. §112, first paragraph

Claims 1-20 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner's justification is as follows (emphasis added):

Regarding claims 1, 2, 5, 6 and 11 it appears that there is no support in the originally filed disclosure for the term: "with no spring return mechanism." The original specification disclose the prior art valve having a return spring mechanism (paragraph 32) and that in the valve of the present invention the return spring mechanism, or the prior art valve, is removed and replaced with a second pneumatic return. However, nowhere in the specification is it disclosed that the valve of the present invention does not have a spring return mechanism. ***Just because the spring return mechanism of the prior art valve is removed and replaced, doesn't mean that there is not spring return mechanism.*** Additionally, the drawings do not appear to show a return spring mechanism, but it is noted that just because the drawings do not show a feature that doesn't mean that that feature is not or never is present.

In this regard, "[t]he fundamental factual inquiry [for determining adequacy of written description] is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. MPEP 2163, citing *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

In the present case, it is respectfully submitted that the disclosure in the original specification that the prior art valve has a return spring mechanism, and that in the valve of the present invention the return spring mechanism of the prior art valve is *removed* and replaced with a second pneumatic return, is fully supportive of a valve "with no spring return mechanism" under the written description. See also *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., 'in the same words'] to be sufficient").

In the Office Action, the Examiner also urges (a) that the applicant argues that the elasticity of the flexible valve diaphragm seals is what causes the valve to return to its default neutral state and (b) the flexible valve diaphragm seals are therefore act as a “spring return mechanisms” and are therefore being considered return spring mechanisms. The “spring return” discussed in the specification, however, is a coil spring return (see paragraph [0032] and Figs. 5 and 6 discussed therein). Thus, in an effort to advance prosecution, claims 1, 2, 5 and 11 have been amended to reflect the absence of this feature.

Reconsideration of the rejection under 35 U.S.C. §112, first paragraph is requested.

Rejection Under 35 U.S.C. §103(a) – Kintner and acknowledged state of the art

Claims 2, 4, 5, 7, 10-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the acknowledged prior art of Figure 1 in view of Kintner (U.S. Patent No. 3,426,799). Claims 1, 3, 6, and 14-20 are rejected as being unpatentable in light of acknowledged prior art of figure 1-8, in view of Kintner.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicant asserts that the Examiner has not satisfied his burden of establishing a *prima facie* case of obviousness based upon the prior art.

The Examiner asserts that applicant’s admitted prior art of Figure 1 (everything but the valve 70) in combination with the valve of Kintner, teaches the claimed invention. Specifically, the Examiner asserts that while the admitted prior art does not specifically disclose that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats, “Kintner shows a pneumatic actuated valve (figures 1 and 2) and a three-way valve (figure 3), both having no spring return mechanism....It would have been obvious to...substitute the new pneumatically actuated three-way valve of Kintner for the three-way valve of figure 1 in order to make the medical device operate more precisely by having a pneumatic return mechanism that can be adjusted.”

The Examiner’s primary argument appears to be that Figure 1 teaches all of the elements of the invention of independent claim 1 except that it fails to teach “that the valve is a pneumatically actuated three-way valve with no spring return mechanism and two valve seats.” To remedy such deficiency, the Examiner then turns to Kintner, a 1969 patent document for an “Automatic Valve.” However, Kintner fails as a primary reference. The valve of Kintner simply

does not disclose a dual pneumatic actuated three-way valve comprising two air pressure diaphragms and two valve seats that is dual actuated with no spring return mechanism.

Upon reviewing the valve device of Kintner in detail, it becomes apparent why the device of Kintner fails to teach the claimed invention and why the combination with the acknowledged prior art fails to establish a *prima facie* case of obviousness. Kintner expressly *teaches away* from valves such as those of the present invention that include air pressure diaphragms and valve seats, dismissing them as undesirable. Instead of valves having seats and diaphragms, Kintner advocates a valve actuated by a “piston which can be moved by application of extremely small pressures to operate the valve” and which dispenses with the need for “costly stems, and unreliable seats and diaphragms.” (col. 1, lines 7-15).

Entirely different in its mechanism from the valves of the present invention, the Kintner valve involves a sliding piston assembly that moves from a default closed “seated position” to an “open position.” Specifically, Kintner teaches “floating O-rings” wrapped around a series of pistons that are mounted on piston rods. In its default state, as shown in Fig. 1 of Kintner, the valve is in the “closed position.” (col. 1, lines 35-37). Then, “[i]n operation, the O-ring actually “floats” radially outwardly as it moves from the position shown in Fig. 1 to that shown in Fig. 2 since the stretched O-ring leaves its seating position during such movement as it slides across the recessed area 16 in the flow stream. Line pressures immediately encapsulate the O-ring.” (col. 2, lines 48-66).

Thus, even if one of skill in the art were assumed to be motivated to combine Kintner with the acknowledged prior art, which that person would not, the result would not be the present invention. There is nothing to support the assertion that the piston-valve of Kintner could result in the claimed three-way valve having “a default neutral state in which all valve seats of said three-way valve remain open when supply pressure operating said valve is removed.” Without any type of force to move the piston, the valve of Kintner would remain in the closed position as discussed above. The Examiner has not shown otherwise.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in*, *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ 1385, 1396 (2007). Applicant respectfully states that the Examiner has neither met his burden of establishing a

prima facie case of obviousness nor provided a rational underpinning to support his legal conclusion of obviousness.

As the Kintner reference, either singly or in combination with the acknowledged prior art, fails to establish a *prima facie* case of obviousness, reconsideration and withdrawal of the rejection as being unpatentable over the cited art, is therefore requested.

Applicant also incorporates by reference the remarks presented in Applicant's response filed October 10, 2006 and March 26, 2007 for the rejection of the claims over Kintner and acknowledged prior art. For at least these reasons, it is respectfully submitted that the rejected claims are patentable over the cited references.

Rejection Under 35 U.S.C. §103(a) – Liston and Kintner

Claims 1-4, 6, 7 and 10-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Liston (U.S. Pat. No. 3,817,425) in view of Kintner. This rejection is respectfully traversed.

Liston fails to correct the deficiency of Kintner, as discussed above. All presently pending claims require a dual pneumatic actuated three-way valve comprising two valve seats. Kintner, on the other hand, does not teach such a valve but rather, teaches piston-operated valves. It is respectfully requested that the remarks presented in Applicant's response filed October 10, 2006 and March 26, 2007 be herein incorporated by reference.

Rejection Under 35 U.S.C. §103(a) – Acknowledged prior art, Liston and Chemline Plastics

Claims 8-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over acknowledged prior art, in view of Kintner, further in view of Chemline Plastics (2001). This rejection is respectfully traversed. Independent claim 5, upon which claims 8-9 depend, is patentable for the reasons discussed above and the rejection of claims 8-9 fails for the same fundamental reasons. In addition, these claims provide further distinguishing features.

CONCLUSION

In light of the foregoing remarks, it is believed that the rejections of record have been obviated, and allowance of this application is respectfully requested. Applicants submit all pending claims are in condition for allowance, early notification of which is earnestly solicited.

Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

Respectfully submitted,

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ATTACHMENT